K113754

5. 510(k) Summary

Owner/Contact:
K. Lance Gould, M.D.
Professor of Cardiovascular Medicine
University of Texas Medical School at Houston
6431 Fannin St., Suite MSB 4.256
Houston, TX 77030
Phone 713 500 6611
Fax 713 500 6615
Email K.Lance.Gould@uth.tmc.edu

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Date of preparation: December 19, 2011

Device trade name: cfrQuant

Common name: Coronary Flow Reserve (CFR) Quantification

Classification names: emission computed tomography system (21 CFR 892.1200, Product Code KPS)

Devices claimed for equivalence:
- K101279, Corridor4DM v2010
- K083327, *syngo*Circulation DynamicPET
- K080770, ImagenMD with ImagenQ

General description: The coronary flow reserve (CFR) quantification (cfrQuant) system is a software package intended for use by nuclear medicine and nuclear cardiology physicians and technologists to perform clinical quantitative analysis on cardiac positron emission tomography (PET) image data. Archiving of output data will be supported for clinical diagnostics, quality control, and research.

cfrQuant calculates absolute myocardial blood flow in cc/min/g using a two-dimensional topographical map of PET tracer uptake and an integrated arterial input value. Absolute myocardial flow is calculated from a mathematical flow model validated using microspheres in animals (see Yoshida, Mullani and Gould in J Nuc Med 37:1701, 1996).

To compute CFR, three inputs are required: integrated arterial activity in the early part after bolus injection, average myocardial activity in the late part after bolus injection, and correction factors for partial volume effects of the PET scanner. The first number comes from a region of interest (ROI) drawn in the thoracic aorta or left atrium on images taken soon after radionuclide bolus administration. The second number comes from the topographic maps of myocardial uptake produced by the Positron CARDIAC software. The third number varies by PET camera and will be initialized in a user preference file.

Intended use: cfrQuant is intended for quantification of absolute myocardial blood flow and coronary flow reserve when applied to diagnostic cardiac PET imaging in patients with suspected or known coronary artery disease.

Technological characteristics: CFR is a software package that uses standard, industrial computing hardware and applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

K. Lance Gould, M.D.
Professor of Cardiovascular Medicine
University of Texas Medical School at Houston
6431 Fannin Street, Suite MSB 4.256
HOUSTON TX 77030

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Re: K113754
Trade/Device Name: cfrQuant (Coronary Flow Reserve Quantification)
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: July 3, 2012
Received: July 6, 2012

Dear Dr. Gould:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4. Indications for Use

510(k) Number: K113754

Device Name: cfrQuant (Coronary Flow Reserve Quantification)

Indications for Use:

The cfrQuant coronary flow reserve (CFR) quantification software quantifies blood flow in the myocardial wall of the heart's left ventricle based on positron emission tomography (PET) images of radionuclide tracer distribution.

The product is intended for use by trained professionals, such as nuclear technicians and nuclear medicine or nuclear cardiology physicians. The clinician remains ultimately responsible for the final assessment and diagnosis based on standard practices and visual interpretation of all PET data.

The software accepts cardiac PET images of either N-13 ammonia or Rb-82 tracer uptake during two physiologic states: baseline (rest) and increased blood flow (stress). A mathematical model computes absolute myocardial perfusion (flow per mass of tissue, or cc/min/gm) at rest and stress. The ratio of stress-to-rest flow is termed the coronary flow reserve (CFR). Visual displays of absolute flow and CFR as well as their numeric quantification are presented to aid diagnostic interpretation of myocardial PET images.

Prescription Use YES
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use NO
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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